

REMARKS

This responds to the Office Action dated October 2, 2006 and supplements the Amendment and Response filed on March 8, 2007.

Claim 149 is added. Claims 1-149 are now pending in this application.

The Nonstatutory Double Patenting Rejections

Claims 1-3, 8-13, 32-34, 39-44, and 63-78 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 28-42 of co-pending application Serial No. 10/890,825. Claims 1-3, 8-10, 13, 32-34, 39-41, and 71-75 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 13 and 15-18 of co-pending application Serial No. 11/220,397. Claims 1-3, 8-9, 13, 32-34, 39-40, 44, 63-64, and 71-75 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 11-13 and 16-17 of co-pending application Serial No. 11/276,077.

Applicant notes that U.S. Patent Application Serial Nos. 10/890,825, 11/220,397 and 11/276,077 have not yet issued and are pending. Therefore, a terminal disclaimer is not required in these matters until issuance of one of them. If a terminal disclaimer is required in any of Serial Nos. 10/890,825, 11/220,397 and 11/276,077, it can be requested by the Office before issuance of those matters.

The 35 U.S.C. § 103 Rejection of the Claims using Soykan and Levine

Claims 1-2, 8, 13, 32-33, 39, 44, 63, 65-67, and 71-73 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. (U.S. published application No. 2001/0000802) in view of Levine et al. (U.S. published application No. 2002/0019350).

Applicant respectfully traverses the rejection and submits that Soykan et al. in combination with Levine et al. do not provide the recited subject matter. For example, Applicant is unable to find in Soykan et al. or Levine et al., among other things, a teaching or suggestion of a gene regulatory signal delivery device that emits a regulatory signal which directly or indirectly

regulates a regulatable transcriptional control element and a controller electrically connected to the gene regulatory signal delivery device, as recited in claims 1 and 32.

Applicant is also unable to find in Soykan et al. or Levine et al. among other things, a teaching or suggestion of a regulatory signal selected to regulate the transcriptional control element in a vector, i.e., regulating gene expression at the level of transcription, as recited in claims 1 and 32.

Regardless of whether Levine et al. provide gene therapy reagents having a promoter, e.g., a promoter responsive to transactivation, chimeric molecules having an angiogenic factor and a vascular endothelium targeting molecule to promote or inhibit angiogenesis, and routes to administer those reagents, neither Soykan et al. nor Levine et al. provide for a device useful to regulate the expression of a genetic vector that is not associated with the device.

Moreover, the disclosure in Levine et al. related to the use of electroporation is to introduce nucleic acid, an angiogenic factor or delivery vehicle to a cell, and the disclosure in Soykan et al. related to electrical stimulation is to release cellular products from cells, such as by triggering secretion, inducing large pores in the cell membrane or destroying the cell membrane (see paragraphs 0036, 0043 and 0072).

Applicant respectfully requests reconsideration and allowance of claims 1-2, 8, 13, 32-33, 39, 44, 63, 65-67, and 71-73.

The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Darvish

Claims 3 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 1 and 32 above, and further in view of Hamm et al. (U.S. published application No. 2004/0030379).

Applicant respectfully traverses the rejection. Claim 3 is dependent on claim 1 and claim 34 is dependent on claim 32. Thus, the discussion above for claims 1 and 32 is incorporated herein to support the patentability of claims 3 and 34.

Applicant respectfully requests reconsideration and allowance of claims 3 and 34.

The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Darvish

Claims 9 and 40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 1, 8, 32 and 39 above, and further in view of Darvish et al. (U.S. published application No. 2002/0183686).

Applicant respectfully traverses the rejection. Claim 9 is ultimately dependent on claim 1 and claim 40 is ultimately dependent on claim 32. Thus, the discussion above for claims 1 and 32 is incorporated herein to support the patentability of claims 9 and 40.

Applicant respectfully requests reconsideration and allowance of claims 9 and 40.

The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Donahue

Claims 10-12 and 41-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 1, 8, 32 and 39 above, and further in view of Donahue et al. (U.S. published application No. 2002/0155101).

Applicant respectfully traverses the rejection. Claims 10-12 ultimately depend on claim 1 and claims 41-43 ultimately depend on claim 32. Thus, the discussion above for claims 1 and 32 is incorporated herein to support the patentability of claims 10-12 and 41-43.

Applicant respectfully requests reconsideration and allowance of claims 10-12 and 41-43.

The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Shelton

Claims 64 and 68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 32, 63 and 67 above, and further in view of Shelton et al. (U.S. Patent No. 5,312,453).

Applicant respectfully traverses the rejection. Claims 64 and 68 ultimately depend on claim 32. Therefore, the discussion above for claim 32 is incorporated herein to support the patentability of claims 64 and 68.

Applicant respectfully requests reconsideration and allowance of claims 64 and 68.

145. (Withdrawn) The method of claim 125 or 126 wherein the system is implanted in or on a blood vessel.

146. (Withdrawn) The method of claim 125 or 126 wherein the open reading frame encodes a dominant negative gene product.

147. (Withdrawn) The method of claim 125 or 126 wherein at least one expression cassette encodes vascular endothelial growth factor 121 (VEGF₁₂₁), protein kinase B (AKt), catalytic subunit of human telomerase (hTERT), connexin43, fibroblast growth factor 4 (FGF-4), hypoxia-inducible transcription factor 1 alpha (HIF-1 α), B cell leukemia protein 2 (Bcl-2), adenylcyclase IV (AC_{VI}), beta adenergetic receptor kinase 1 (β ARK-1), beta-adrenergic receptor (β -AR), vasopressin receptor 2 (V₂), sarcoplasmic reticulum Ca²⁺ ATPase (Serca2A) or phospholamban.

148. (Withdrawn) The method of claim 125 or 126 wherein the animal is a mammal.

149. (New) The system of claim 1 wherein the controller is electrically wired to the gene regulatory signal delivery device.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

STEVEN D. GIROUARD ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6959

Date

April 19, 2007

By

Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EES-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19 day of April, 2007.

Name

Paula Secomy

Signature

Paula Secomy